

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Whirley et al.

Examiner: Thomas Sweet

Application No.: 10/769,532

Group Art Unit: 3774

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For: INFLATABLE POROUS IMPLANTS AND
METHODS OF DRUG DELIVERY

Dated: March 1, 2010

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APPEAL BRIEF PURSUANT TO 37 C.F.R. §41.37

Sir:

The Appellant has appealed the Examiner's Final Rejection of Claims 1-9, 11-14, 18, 19, 21, 36, 39, and 41-56 dated May 22, 2009. This Appeal Brief is submitted in accordance with the provisions of 37 C.F.R. §41.37. As required by 37 C.F.R. §41.37(a)(2), please charge Deposit Account No. 08-2461 the requisite fee of \$540.00 for submitting this Appeal Brief. If additional fees are required, please charge Deposit Account No. 08-2461. The Appellant has filed a timely Notice of Appeal on August 21, 2009. This Appeal Brief is being filed in support of the Notice of Appeal.

I. Real Party In Interest

The real party in interest is TriVascular2, Inc., the assignee of the entire right, title and interest in and to Application No. 10/769,532.

II. Related Appeals and Interferences

No related appeals or interferences are known to the Appellants or the Appellants' legal representative that will directly affect or be directly affected by or have bearing on the Board's decision in this appeal.

III. Status of Claims

Claims 1-9, 11-14, 18, 19, 21, 36, 39, and 41-56 are presently pending in the application. Claims 10, 15-17, 20, 22-35, 37-38, and 40 are canceled. Claims 1-9, 11-14, 18, 19, 21, 36, 39, and 41-56 stand as being finally rejected. These rejected claims, i.e., claims 1-9, 11-14, 18, 19, 21, 36, 39, and 41-56, are being appealed.

IV. Status of Amendments

On July 22, 2009, a submission entitled Amendment and Response to Final Office Action was filed in response to the final Office Action mailed on May 22, 2009. Although this submission was entitled an Amendment and Response to Final Office Action, no amendments were presented therein. In this regard, the Response did not amend any claims, but argued for patentability of the claims. Accordingly, no amendments were presented subsequent to the final

rejection. Moreover, no amendments were presented after the Notice of Appeal was filed on August 21, 2009.

The Response which was filed on July 22, 2009, was a request for reconsideration of the claims. In an Advisory Action mailed on August 12, 2009, the Examiner indicated that the request for reconsideration had been considered, but was deemed by the Examiner not to place the application in condition for allowance. As such, the Response filed on July 22, 2009, has been acted upon by the Examiner and entered.

V. Summary of Claimed Subject Matter

The present invention, as set forth in independent **claim 1**, is directed to a graft (10) which includes a graft body section (16) having a proximal end (13), a distal end (15). (Fig. 1, para. [0013], lines 1-3, para. [0035] lines 1-5.) The graft body section (16) defines at least one inflatable porous channel (20). (Fig. 1, para. [0013], lines 2-4; para. [0035] lines 7-9.) The graft (10) further includes at least one inflatable porous cuff (26) which is disposed at the proximal (13) or distal end (15) of the graft body section (16). (Fig. 1, para. [0016], lines 10-12.) The inflatable porous cuff (26) is in fluid communication with the at least one inflatable porous channel (20). (Fig. 1, para. [0016], lines 12-14.) The at least one inflatable porous cuff (26) is disposed in an axisymmetric cylindrical manner around the proximal (13) or distal end (15) of the graft body section (16). (Fig. 1, para. [0039]; lines 3-4.) The graft (10) further includes an inflation medium (22) which including at least one therapeutic agent (46) configured to be

introduced into the inflatable channel (20). (para. [0035], lines 12-14.) The inflation medium (22) includes a curable liquid (para. [0018], lines 19-20); para. [0044], lines 11-12), which includes a therapeutic agent-carrying host polymer (para. 17, lines 1-2); para. [0045], lines 1-3).

Claims 2-9, 11-14, 18, and 19 variously depend from claim 1.

The present invention, as set forth in independent **claim 21**, is directed to a graft (10) which includes a graft body section (16) having a proximal end (13), a distal end (15), and defining at least one inflatable porous channel (20) therebetween. (Fig. 1, para. [0013], lines 1-4, para. [0035] lines 1-9.) The graft (10) includes a connector member (30) affixed to the proximal (13) or distal end (15) of the graft body section (16). The connector member (30) includes one or more connector elements. (para. [0019], lines 4-7; para. [0034], lines 30-32; para. [0043].) The graft (10) also includes a stent (32). The stent (32) includes one or more proximal stent connector elements. (para. [0019], lines 7-9.) The proximal stent connector elements are coupled to the one or more connector member connector elements. (shown in Fig. 1; para. [0019], lines 4-9). The stent (32) includes a multi-crown configuration. (para. [0019], lines 7-9, para. [0034], lines 30-32, para. [0043]). The graft (10) also includes a curable inflation medium (22). (para. [0035], lines 12-14.) The curable inflation medium (22) includes at least one therapeutic agent (46) configured to be introduced into the inflatable channel (20). (para. [0018], lines 19-20); para. [0044], lines 11-12).

Claim 36 depends from claim 21.

The present invention, as set forth in independent **claim 39**, is directed towards a graft (10) which includes a graft body section (16) having a proximal end (13), a distal end (15), and defining at least one inflatable porous channel (20). (Fig. 1, para. [0013], lines 1-4, para. [0035] lines 1-9.) The graft (10) includes at least one inflatable porous cuff (26) disposed at the proximal (13) or distal end (15) of the graft body section (16). (Fig. 1, para. [0016], lines 10-12.) The inflatable porous cuff (26) is in fluid communication with the at least one inflatable porous channel (20). (Fig. 1, para. [0016], lines 12-14.) The at least one inflatable porous cuff (26) is disposed in an axisymmetric cylindrical manner around the proximal end (13) of the graft body section (16). (Fig. 1, para. [0039]; lines 3-4.) The graft (10) also includes a connector member (30) affixed to the proximal (13) or distal end (15) of the graft body section (16). (para. [0019], lines 4-7; para. [0034], lines 30-32; para. [0043].) The connector member (30) includes one or more connector elements. (para. [0019], lines 4-7; para. [0034], lines 30-32; para. [0043].) The graft (10) also includes a stent (32) includes one or more proximal stent connector elements coupled to the one or more connector member connector elements, wherein the stent comprises a multi-crown configuration. (para. [0019], lines 7-9, para. [0034], lines 30-32, para. [0043]). The graft (10) also includes an inflation medium (22) which includes at least one therapeutic agent (46) configured to be introduced into the inflatable channel (20). (para. [0018], lines 19-20); para. [0044], lines 11-12). The inflation medium (22) includes a curable liquid. (para. [0018], lines 19-20); para. [0044], lines 11-12.)

Claims 41-56 depend variously from claim 39.

VI. Grounds of Rejection to be Reviewed on Appeal

The following grounds of rejection are to be reviewed on this Appeal:

I. Whether claims 1-9, 11-14, 18, 19, 21, 36, 39, and 41-56 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent Application Publication No. 2002/0103527 to Kocur et al. (hereinafter Kocur) in view of WO 99/39662 to Chobotov (hereinafter Chobotov) and US 6,051,648 to Rhee et al. (hereinafter Rhee)?

II: Whether U.S. Patent 6,051,648 to Rhee is admitted prior art, or, as Official Notice that was not rebutted?

VII. Argument

I. Rejection under 35 U.S.C. §103(a) over U.S. Patent Application Publication No. 2002/0103527 to Kocur in view of WO 99/39662 to Chobotov and US 6,051,648 to Rhee.

Claims 1-9, 11-14, 18, 19, 21, 36, 39 and 41-56 are pending. In the present action, the Examiner has rejected claims 1-9, 11-14, 18, 19, 21, 36, 39 and 41-56 as allegedly obvious under 35 U.S.C. §103(a) from US 2002/0103527 to Kocur et al. (hereinafter “Kocur”) in view of WO 99/39662 to Chobotov (hereinafter “Chobotov”) and US 6,051,648 to Rhee et al. (hereinafter “Rhee”). Applicants respectfully request reconsideration in light of the following arguments.

Kocur is directed to a stent having a pocket for containing and delivering a biological agent. Kocur teaches that a therapeutic agent may be used within a channel or fold of its graft. As acknowledged by the Examiner, Kocur fails to disclose, teach or suggest the use of a an inflation medium which includes a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer, as set forth in independent claims 1, 21, and 39 of the subject application. Thus, Kocur is completely silent as to an inflation medium comprising a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer may be useful for delivery of its therapeutic agent through the wall of its graft to the tissue of a bodily lumen as set forth in independent claims 1, 21, and 39.

Chobotov is directed to an endovascular graft having, *inter alia*, inflatable cuffs and channel(s).

The Examiner looks to Rhee to cure the deficiencies of Kocur, alleging that “Rhee et al demonstrates the use of host polymer (polyethylene glycol, a curable liquid) for containing bioactive material(s) in conjunction with a graft”, citing Col. 18, line 21 of Rhee.

Respectfully, the Examiner’s interpretation of Rhee is incorrect.

Rhee is directed to “crosslinked polymer compositions ... as bioadhesives ... and as drug delivery matrices....” (Rhee, column 1, lines 13-21). The compositions of Rhee are “not readily degradable in vivo....” (Rhee, column 3, line 60). The bioadhesives are specifically formulated for “effecting temporary or permanent attachment between the surfaces of two native tissues, or between a native tissue surface and a non-native tissue surface or a surface of a synthetic

implant. (Rhee, column 16, lines 64-67). “Synthetic implants [may] include vascular grafts, stents, and stent/graft combinations....” (Rhee, column 18, lines 18-21).

The Examiner asserts that Rhee teaches the use of a cross-linking host polymer for containing bioactive materials in conjunction with a graft at column 18, line 21. The Examiner, however, expressly ignores the other teachings of Rhee directed to that very embodiment cited by the Examiner. For example, Rhee specifically requires that its cross-linking polymer containing a bioactive substance must contact a native tissue surface. (Rhee, column 17, lines 60-61). In addition to contacting a native tissue surface, Rhee’s polymer may also contact a non-native surface, such as a stent-graft. (Rhee, column 18, lines 5-21). Thus, Rhee fails to teach or suggest that its curable compositions will be useful for transporting a therapeutic agent to native tissue where its composition fails to contact such native tissue. In other words, there is not teaching, suggestion and/or expectation in Rhee that its compositions may be used within the inflatable channel of the present invention.

Applicant respectfully asserts that the Examiner’s construction of Rhee is improper as it picks and chooses from the disclosure to support Examiner’s own allegations while ignoring the actual disclosure and primary purpose of the Rhee. The portion of text to which the Examiner refers is under the heading of “Use of the Crosslinked Synthetic Polymers as Bioadhesives”. (Col. 16, lines 56-57).

Rhee defines the terms “bioadhesive” and biological adhesive”, and “surgical adhesives” as interchangeable terms to “refer to biocompatible compositions capable of

effecting temporary or permanent attachment between the surfaces of two native tissues, or between a native tissue surface and a non-native tissue surface or surface or a surface of a synthetic implant.” (Col. 16, lines 62-67, emphasis added). The bioadhesive can be used between:

- (1) two native tissues;
- (2) a native tissue surface and a non-native tissue surface; and
- (3) a native tissue surface and a surface of a synthetic implant.

Looking within the same discussion, there is further support to the assertion that the Examiner has improperly construed Rhee, as it provides, at least one of the first and second surfaces is “a native tissue surface” while “[t]he other surface may be a native tissue surface, a non-native tissue surface, or a surface of a synthetic implant.” (Col. 17, lines 60-61, Col. 18, lines 5-6). Rhee defines a synthetic implant as “grafts, stents, and stent/graf [sic] combinations” (Col. 18, lines 20-21). Thus, Rhee discloses the use of two cross-linked synthetic polymers to adhere a native tissue to a native tissue, a non-native tissue, or a synthetic implant. Thus, Rhee specifically requires that its cross-linking polymer containing a bioactive substance must contact a native tissue surface. (Rhee, column 17, lines 60-61). It should be noted that Rhee is silent as to using biological agents when adhering a native tissue to a second surface. There is absolutely no teaching, suggestion, or motivation in Rhee to use an inflation medium which includes a therapeutic agent and a curable liquid comprising a

therapeutic agent-carrying host polymer in a graft, or that Rhee's compositions may be used within the inflatable channel of the present invention as set forth in independent claims 1, 21, and 39 of the subject application. Thus, Rhee fails to remedy the deficiencies of Kocur. Therefore, claims 1, 21, 39, and the claims which depend therefrom are patentably distinct and are not obvious in view of Kocur, Chobotov, and Rhee, taken individually and in combination thereof.

As Kocur fails to teach or suggest an inflation medium comprising a curable liquid comprising a therapeutic agent-carrying host polymer, as set forth in the independent claims of the subject application, may be useful with its channel, there is no motivation to alter the specific teachings of Rhee. In other words, Kocur teaches that a therapeutic agent may be used within a channel of fold of its graft. Kocur fails to teach or suggest that an inflation medium comprising a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer may be useful for delivery of its therapeutic agent through the wall of its graft to the tissue of a bodily lumen.

In establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* It is only through hindsight reconstruction and selective picking and choosing does the Examiner attempt to reach the present invention through the combination of Kocur, Chobotov and Rhee. It is also well established,

however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness, and any attempt at hindsight reconstruction using Appellant's disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993). Such hindsight reconstruction by the Examiner is clear as Kocur, Chobotov and Rhee fail to teach or suggest the limitations of the subject invention. Indeed, the only teaching of the use of an inflation medium comprising a therapeutic agent and a curable liquid comprising a therapeutic agent-carrying host polymer within an inflatable porous channel of a graft is the subject application.

Moreover, the Supreme Court addressed the standard for obviousness in its decision of *KSR International Co. v. Teleflex Inc., et al.*, 550 U.S. 389; 127 S.Ct. 1727; 167 L.Ed.2d 705; 82 U.S.P.Q.2d 1385 (2007). In order for an Examiner to establish a *prima facie* case of obviousness after *KSR*, some degree of predictability is necessary. (82 U.S.P.Q.2d at 1395-97). *Takeda Chemical Industries Ltd. V. Alphapharm Pty. Ltd.*, 83 USPQ.2d 1169 (Federal Circuit 2007) is a post *KSR* decision in which the Federal Circuit articulated standards for establishing non-obviousness which again includes predictability of success. (83 USPQ.2d at 1176-79). Further, Section 2143.02 (II) of the MPEP states that "Obviousness does not require absolute predictability, however, at least some degree of predictability is required."

Clearly, the disclosures of Kocur, Chobotov and Rhee do not provide sufficient predictability or expectation to support a *prima facie* case of obviousness as none of these references, individually or in combination, disclose, teach or suggest the use of an inflation medium comprising a therapeutic agent and a curable liquid comprising a therapeutic agent-

carrying host polymer within an inflatable porous channel of a graft. As none of these references, individually or in combination, disclose, teach or suggest the present invention, the Examiner must provide some reasoning with some degree of predictability of success that one of ordinary skill in the art would modify Kocur, Chobotov and Rhee in an attempt to arrive at the present invention. In particular, the Examiner offers no reasoning to modify the specific teaching of Rhee that requires its curable compositions to be in direct contact with native tissue so that its bioactive agent within its composition may be used. There is no other reference of record that teaches or suggests that the compositions of Rhee may somehow be modified so they do not have to contact native tissue and still be useful for their intended purpose.

The expectation and predictability to arrive at the present invention through Kocur, Chobotov and Rhee do not rise to a level that represents a *prima facie* case of obviousness. It is only through impermissible hindsight reconstruction by using the subject application as a roadmap does the Examiner attempt to present a *prima facie* case of obviousness.

II: Rejection of Claims citing Rhee is cited as admitted prior art, or Examiner's "Official Notice" that was not addressed by Applicant.

In reference to Rhee, the Examiner incorrectly alleged in the final office action that, as Applicant has failed to address the Examiner's argument cited with respect to "Official Notice", Rhee was admitted prior art against Applicant. In the previous action, the Examiner cited Rhee as documentary evidence, not official notice. Citing a reference as documentary evidence of an

assertion is the clearly not “official notice”. Official notice is where, in certain circumstances, an Examiner may “state facts not in the record or rely on common knowledge in making a rejection”, where such “notice of facts [is done] without supporting documentary evidence” or reference. MPEP §2144.03 (internal marks omitted). When an Examiner provides a citation for an assertion, Applicant respectfully asserts that this is clearly not “official notice”.

In relying on Rhee in furtherance of the Examiner’s rejection, the Examiner did not use “official notice”; but rather, used “documentary evidence”. Applicant fully traversed Examiner’s interpretation of Rhee in the response to office action filed on January 29, 2009, alleging, *inter alia*, that Rhee was improperly combined with Chobotov and Kocur in the Examiner’s alleged §103 references, and that the Examiner failed to state a *prima facie* obviousness case, in favor of the rejections being withdrawn. Thus, Applicant did address the Examiner’s allegation of the disclosures of Rhee.

The Examiner alleged that Applicant did not address the “official notice” taken in the office action response of January 29, 2009 and thus, further alleged that the Examiner’s reasoning is admitted prior art. This is impermissible and is clearly not the case. For the reasons set forth above, Applicant did challenge the Examiner’s characterization of Rhee and specifically addressed the deficiencies of Rhee in the previous response. Applicant’s arguments were directed, *inter alia*, to respectfully traversing the Examiner’s incorrect assertion that “Rhee demonstrates the use of host polymer ... for containing bioactive material(s) in conjunction with a graft.” The traversal with supporting arguments of the Examiner’s incorrect interpretation of

Rhee further refutes any reasoning the Examiner used to combine Rhee with Kocur and Chobotov and compounds the deficiencies of these references as applied to claims 1, 21, and 39 of the present invention.

Assuming *arguendo*, the Examiner did cite Rhee as “official notice”, before the Examiner’s official notice can be made admitted prior art against Applicant, the Examiner is required to include an explanation as to why the traversal of official notice was inadequate. MPEP §2144.03(c). No such explanation was included as the Examiner merely impermissibly concluded that “official notice was not addressed”.

Thus, Applicant respectfully traverses the Examiner’s statements with respect to Rhee being admitted prior art to the present invention and Applicant respectfully requests clarification of the record regarding the same. At the present case, the Examiner has incorrectly referenced and alleged “documentary evidence” as “official notice”. As Examiner’s previous assertion was not done through “official notice” and as Applicant has not made any express statement during prosecution identifying Rhee as “prior art” to the present application, Rhee is clearly not admitted prior art. Such a characterization is improper and is in direct conflict with the Manual of Patent Examining Procedure. MPEP §706.02(III), MPEP §2129 (I).

In the advisory action dated August 12, 2009, the Examiner attempts to remedy the previously incorrect allegations set forth in the final office action with respect to the “official notice” arguments, as the Examiner further alleged that, with respect to “official notice”, the rejection was two-pronged, including both official notice and evidence. The Examiner alleged

that since “there is both official notice and evidence” and “the official notice was not addressed, it is now prior art”. To allow such hindsight reconstruction of a rejection is inherently improper and should not be allowed for public policy reasons. Where Rhee has been cited against one or more of the claims of the present invention, the Examiner has done so with citation to Rhee (the Examiner cites either the background of the invention or Col. 18, line 21). Applicant has addressed the disclosures and deficiencies of Rhee, even going to far as to expand upon the sections cited by the Examiner to illustrate that Rhee is not relevant to the present invention as set forth in independent claims 1, 21, and 39.

It is impermissible for an Examiner to allege that an Applicant has not addressed an Official Notice statement, when an Examiner has never indicated that a cited statement is in fact a dual-pronged rejection. The words “official notice” did not appear in the official action upon which the Examiner relies. Thus, at no point was Applicant given “official notice”. Further, the Examiner provided citations to the Rhee reference, several times, throughout the course of prosecution. This is documentary evidence. Allowing an Examiner to ignore the line by line quotations of the references actual disclosure and teachings by relying on “official notice” as “admitted prior art” goes against the foundations of patent law and, in fact, ignores the principles and procedures of determining “prior art” within the confines of Chapter 900 Manual of Patent Examining Procedure. If this rejection is allowed to stand, no matter how incorrect an Examiner’s interpretation of a reference is, Applicant will not be permitted to correct an incorrect interpretation of the reference, no matter how clear or plain the error.

For these reasons, Applicant respectfully requests that the Applicant respectfully requests that the application of Rhee through “official notice” and as “admitted prior art” be immediately withdrawn in order to correct and clarify the record. Further, upon a review of the actual teachings and lack of teachings of Rhee, Applicant respectfully asserts that Rhee fails to correct the deficiencies of Kocur, Chobotov. Thus, independent claims 1, 21 and 39, and the claims which depend therefrom, are patentably distinct over Kocur, Chobotov and Rhee, taken individually or in combination. Therefore, withdrawal of the obviousness rejections of these claims is respectfully requested.

Thus, for the reasons set forth herein, claims 1-9, 11-14, 18, 19, 21, 36, 39, and 41-56 are patentably distinct from the applied art as set forth by the Examiner in the Final Office Action. Reconsideration and withdrawal of the rejections of claims 1-9, 11-14, 18, 19, 21, 36, 39, and 41-56 are respectfully requested.

Respectfully submitted,



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VIII. Claims Appendix

Claim 1. (Previously presented): A graft comprising:

a graft body section having a proximal end, a distal end, and defining at least one inflatable porous channel;

at least one inflatable porous cuff disposed at the proximal or distal end of the graft body section and in fluid communication with the at least one channel, wherein the at least one inflatable porous cuff is disposed in an axisymmetric cylindrical manner around the proximal or distal end of the graft body section; and

an inflation medium including at least one therapeutic agent configured to be introduced into the inflatable channel;

wherein the inflation medium comprises a curable liquid comprising a therapeutic agent-carrying host polymer.

Claim 2. (Original): The graft of claim 1 wherein the agent is capable of being transported from the inflation medium through a wall of the porous channel and released into a body lumen.

Claim 3. (Original): The graft of claim 2 wherein the agent is configured to be released into the body lumen from a luminal or abluminal surface of the graft body section.

Claim 4. (Original): The graft of claim 2 wherein the porous channel has varying levels of porosity.

Claim 5. (Original): The graft of claim 2 wherein the graft body section comprises one or more materials selected from the group consisting of a fluoropolymer, a polyethyleneterephthalate, a polyvinylchloride, a polyurethane, a polyolefin, and a polyamide.

Claim 6. (Original): The graft of claim 2 wherein the graft body section comprises expanded or perforated polytetrafluoroethylene.

Claim 7. (Original): The graft of claim 2 wherein a quantity of the agent releasable into the body lumen ranges from about 10 micrograms to about 100 milligrams.

Claim 8. (Original): The graft of claim 2 wherein the therapeutic agent is configured to be transported into the body lumen in a time period ranging from about seven days to about twelve months.

Claim 9. (Original): The graft of claim 2 wherein the at least one therapeutic agent comprises one or more agents selected from the group consisting of an endothelialization promoting agent, an angiogenesis promoting agent, an anti-thrombotic agent, an anti-

aneurysmal agent, an anti-infection agent, an anti-inflammatory agent, an anti-restenosis agent, a chemotherapeutic agent, and an anti-cancer agent.

Claim 10. (Canceled)

Claim 11. (Previously presented): The graft of claim 1 wherein the therapeutic agent is capable of being released by diffusion through the host polymer.

Claim 12. (Previously presented): The graft of claim 1 wherein the therapeutic agent is capable of being released by degradation of the host polymer.

Claim 13. (Previously presented): The graft of claim 1 wherein the graft body section comprises biocompatible material capable of inhibiting transport of a bulk of the host polymer.

Claim 14. (Previously presented): The graft of claim 1 wherein the host polymer is capable of being introduced into the inflatable channel before, during, or after graft deployment or implantation.

Claims 15-17. (Canceled)

Claim 18. (Previously presented): The graft of claim 1 wherein the inflation medium has a cure time ranging from about three minutes to about twenty minutes and a post-cure elastic modulus ranging from about 50 psi to about 400 psi.

Claim 19. (Original): The graft of claim 1 wherein the channel comprises one or more features selected from the group consisting of helical spirals, longitudinal channels, and circumferential rings.

Claim 20. (Canceled)

Claim 21. (Previously presented): A graft comprising:

a graft body section having a proximal end, a distal end, and defining at least one inflatable porous channel therebetween;

a connector member affixed to the proximal or distal end of the graft body section, the connector member comprising one or more connector elements;

a stent comprising one or more proximal stent connector elements coupled to the one or more connector member connector elements wherein the stent comprises a multi-crown configuration; and

a curable inflation medium including at least one therapeutic agent configured to be introduced into the inflatable channel.

Claims 22-35 (Canceled)

Claim 36. (Previously presented): The graft of claim 21, wherein the curable inflation medium comprises a curable liquid.

Claims 37-38. (Canceled)

Claim 39. (Previously presented): A graft comprising:

a graft body section having a proximal end, a distal end, and defining at least one inflatable porous channel;

at least one inflatable porous cuff disposed at the proximal or distal end of the graft body section and in fluid communication with the at least one channel, wherein the at least one inflatable porous cuff is disposed in an axisymmetric cylindrical manner around the proximal end of the graft body section;

a connector member affixed to the proximal or distal end of the graft body section, the connector member comprising one or more connector elements;

a stent comprising one or more proximal stent connector elements coupled to the one or more connector member connector elements wherein the stent comprises a multi-crown configuration; and

an inflation medium including at least one therapeutic agent configured to be introduced into the inflatable channel;

wherein the inflation medium comprises a curable liquid.

Claim 40. (Canceled)

Claim 41 (Previously presented): The graft of claim 1 wherein the at least one inflatable porous cuff is disposed at the proximal end of the graft body section and further comprising at least one second inflatable porous cuff disposed at the distal end of the graft body section in fluid communication with the at least one channel, wherein the at least one second inflatable porous cuff is disposed in an axisymmetric cylindrical manner around the distal end of the graft body section.

Claim 42. (Previously presented): The graft of claim 21 wherein the connector member comprises a multi-apex configuration.

Claim 43. (Previously presented): The graft of claim 42 wherein the connector member comprises a twelve-apex configuration.

Claim 44. (Previously presented): The graft of claim 21 wherein the stent comprises a three-crown portion.

Claim 45. (Previously presented): The graft of claim 21 wherein the stent comprises a six-crown portion.

Claim 46. (Previously presented): The graft of claim 21 wherein the stent comprises a three-crown portion and a six-crown portion.

Claim 47 (Previously presented): The graft of claim 21 wherein the connector member affixed to the proximal end of the graft body section; and further comprising
a second connector member affixed to the distal end of the graft body section, the second connector member comprising one or more second connector elements; and
a second stent comprising one or more proximal second stent connector elements coupled to the one or more second connector member connector elements, wherein the second stent comprises a multi-crown configuration.

Claim 48. (Previously presented): The graft of claim 21 wherein the at least one therapeutic agent comprises one or more agents selected from the group consisting of an endothelialization promoting agent, an angiogenesis promoting agent, an anti-thrombotic agent, an anti-aneurysmal agent, an anti-infection agent, an anti-inflammatory agent, an anti-restenosis agent, a chemotherapeutic agent, and an anti-cancer agent.

Claim 49 (Previously presented): The graft of claim 39 wherein the at least one inflatable porous cuff is disposed at the proximal end of the graft body section and further comprising at least one second inflatable porous cuff disposed at the distal end of the graft body section in fluid communication with the at least one channel, wherein the at least one second inflatable porous cuff is disposed in an axisymmetric cylindrical manner around the distal end of the graft body section.

Claim 50. (Previously presented): The graft of claim 39 wherein the connector member comprises a multi-apex configuration.

Claim 51. (Previously presented): The graft of claim 50 wherein the connector member comprises a twelve-apex configuration.

Claim 52. (Previously presented): The graft of claim 39 wherein the stent comprises a three-crown portion.

Claim 53. (Previously presented): The graft of claim 39 wherein the stent comprises a six-crown portion.

Claim 54. (Previously presented): The graft of claim 39 wherein the stent comprises a three-crown portion and a six-crown portion.

Claim 55 (Previously presented): The graft of claim 39 wherein the connector member affixed to the proximal end of the graft body section; and further comprising

a second connector member affixed to the distal end of the graft body section, the second connector member comprising one or more second connector elements; and

a second stent comprising one or more proximal second stent connector elements coupled to the one or more second connector member connector elements, wherein the second stent comprises a multi-crown configuration.

Claim 56. (Previously presented): The graft of claim 39 wherein the at least one therapeutic agent comprises one or more agents selected from the group consisting of an endothelialization promoting agent, an angiogenesis promoting agent, an anti-thrombotic agent, an anti-aneurysmal agent, an anti-infection agent, an anti-inflammatory agent, an anti-restenosis agent, a chemotherapeutic agent, and an anti-cancer agent.

Application No.: 10/769,532
Appeal Brief dated March 1, 2010
Docket No.: 1880-17 RCE III
Page 26

IX. Evidence Appendix

There were no declarations or other evidence submitted during the prosecution of this application.

Application No.: 10/769,532
Appeal Brief dated March 1, 2010
Docket No.: 1880-17 RCE III
Page 27

X. Related Proceedings Appendix

None